K001884

OCT 25 2000

SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

14.1 SUBMITTER INFORMATION

a. Company Name: Flexible Dimensions L.L.C.

b. Company Address: 895 Country Club Road, Suite B100
Eugene, OR 97401

c. Company Phone: (541) 344-5876
Company Facsimile: (541) 431-1187

d. Contact Person: Thomas Gaskill
Vice President, Sales and Marketing

e. Date Summary Prepared: June 19, 2000

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name: Direct Crown

b. Classification Name: Temporary Crown and Bridge Resin
21 CFR 872.3770

14.3 IDENTIFICATION OF PREDICATE DEVICES

The Direct Crown is composed of preformed tooth shells and resin for the fabrication of temporary crowns and bridges. The tooth shells are substantially equivalent to the Harry J. Bosworth Company, "B-Crowns" and the resin is substantially equivalent to both the GC America Alike Resin and the Parkell SNAP Provisional Crown and Bridge Resin. All three predicate devices are commercially available in the United States.

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14.4 DEVICE DESCRIPTION

The Direct Crown system consists of preformed tooth shells and resin for the fabrication of temporary crowns and bridges. The tooth shells are constructed of polycarbonate and are available in a number of sizes for bicuspid and molar teeth. The preformed bridge is a 4-tooth unit that is also available in various sizes. The Direct Crown resin is a methyl methacrylate.

14.5 SUBSTANTIAL EQUIVALENCE

The Direct Crown tooth shells are substantially equivalent to the Harry J. Bosworth "B-Crowns". The fundamental technical characteristics are similar: the Direct Crown tooth shells are equivalent in materials, design, function and intended use to the predicate device.

The Direct Crown resin is substantially equivalent to the GC America Alike Resin and the Parkell SNAP Provisional Crown and Bridge Resin. The fundamental technical characteristics are similar: the resin is equivalent in materials, function, intended use and cure rate as the predicate devices.

14.6 INDICATIONS FOR USE

The Direct Crown is intended for the fabrication of temporary crowns and bridges using the Direct Crown shell teeth and resin.

14.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Direct Crown with the predicate devices is provided within this submission. Both the Direct Crown and the predicate devices are similar in design, materials, intended use and functionality. The preformed tooth shells are constructed of durable polycarbonate and the self-curing resin formulation provides a quick cure rate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2000

Flexible Dimensions LLC
C/O Ms. Carol Patterson
President
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K001884
Trade Name: Direct Crown
Regulatory Class: II
Product Code: EBG
Dated: October 13, 2000
Received: October 17, 2000

Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for _in vitro_ diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001884

INDICATION FOR USE

510(k) Number: K001884

Device Name: Direct Crown

Indications for Use: Direct Crown is intended for the fabrication of temporary crowns and bridges using the Direct Crown shell teeth and resin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sandra L. Shure, DMD - for MSR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001884

Prescription Use ✓ OR Over-The-Counter Use ________
(Per 21 CFR 801.109)